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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------------------|---------------------|------------------|
| 09/445,297 | 12/02/1999 | ROGER PETRUS GEREBERN VANDECRUY'S | JAB-1282 | 9783 |

7590 02/26/2003

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/26/2003

Ub

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------|---------------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/445,297 | VANDECROUYS, ROGER PETRUS GEREBERN | |
| | Examiner Todd D Ware | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 March 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,4-16 and 20-22 is/are pending in the application.
 - 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2,4-16,20 and 22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|--|
| <ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | <ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Receipt of amendment filed 11-26-02 is acknowledged. Claim 22 has been amended as requested.

Election/Restrictions

1. This application contains claim 21 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 2, 4-16, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badwan et al (5,646,131; hereafter '131).**

4. '131 teaches poorly water soluble active agent compositions comprising, a cyclodextrin, a water soluble acid, and a water soluble organic polymer wherein, except for the water soluble acid, the amounts of these ingredients are within the instant ranges (abstract; C 3, L 58-63; C 4, L 6-21 and 62-67; C 5, L 5-9 and 24-44; C 6, L 18-29; Example 4). '131 does, however, teach that the acid must be in sufficient quantity to form aggregates in order for enhancement of solubility to occur.

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5. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to adjust the amount of water soluble acid in the formulation of '844 with the motivation of providing sufficient quantity of acid to form aggregates for enhancement of solubility. Regarding the release profile, '131 does not teach that the release profile would differ from the instant release profile and it is submitted that motivation to adjust the amounts of ingredients within the instant claimed ranges is provided. Therefore, the burden is shifted to the Applicant to demonstrate that the release profile is different, since the Patent Office is not equipped to manufacture products put before it and then obtain prior art products and make physical comparisons therewith.

6. **Claims 2, 4-16, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Sousa Goucha Jorge (EP 0 689 844; hereafter '844) in view of Badwan et al (5,646,131; hereafter '131).**

7. '844 teaches poorly water soluble active agent compositions comprising, a cyclodextrin, a water soluble acid, and a water soluble organic polymer wherein, except for the water soluble acid, the amounts of these ingredients are within the instant ranges (abstract; page 2, lines 25-43; page 3, lines 4-14; example 7; claims). As stated, '844 does not specifically teach or disclose that the amount of the water soluble acid is within the newly claimed range of 35 to 95%. It also does not specifically set forth the instant release profile.

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8. '131 is relied upon for teaching that the inclusion of the same acids as set forth in the instant specification in poorly water soluble drug, cyclodextrin, and polymer formulations enhances the solubilization of the poorly water soluble drug.

9. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to adjust the amount of water soluble acid in the formulation of '844 with the motivation of providing sufficient quantity of acid to form aggregates for enhancement of solubility to occur. Regarding the release profile, neither reference provides indication of a release profile that would differ from the instant release profile and it is submitted that motivation to adjust the amounts of ingredients within the instant claimed ranges is provided. Therefore, the burden is shifted to the Applicant to demonstrate that the release profile is different, since the Patent Office is not equipped to manufacture products put before it and then obtain prior art products and make physical comparisons therewith.

Response to Arguments

10. Applicant's arguments filed 11-26-02 as applied to the new rejection have been fully considered but they are not persuasive. Applicant argues that there is no teaching in '844 to motivate one of ordinary skill in the art to arrive at an amount of water soluble acid within the newly claimed range. In response, it is submitted that '131 provides motivation to adjust the amount of water soluble acid in accordance with the motivation of providing sufficient quantity of acid to form aggregates for enhancement of solubility to occur.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

GS
Gulammali S. Moshref, PhD
Primary Examiner
Group 1600

tw

February 24, 2003